REMARKS

Withdrawn Claims 36-56

In the Office Action, claims 36-56 are woithdrawn from consideration as allegedly being drawn to a separate invention. Further, it is argued that these claim would require a separate search. However, these are merely conclusions. No rationale is provided in support of these conclusions.

Independent claims 36, 37, 38, and 56 are all directed to a method of contraception in a female mammal. The same is true for elected independent claim 14. Claims 36, 37, 38, and 56 all recite, during a period of at least 28 days (e.g., 28-84 days), administering a gestagen and during the last 5-10 days of the period administering a gestagen and a natural estrogen. The same is true for elected independent claim 14.

Thus, it is a clear that the subject matter of claims 36, 37, 38, 56, and the claims dependent thereon is undeniably related to the subject matter being examined. There is nothing of record to support the allegation that a separate search is required. There is nothing of record to support that there is any serious burden imposed on the Examiner in examining these claims with the elected subject matter.

Withdrawal of the holding of claims 36-56 as being withdrawn from consideration is respectfully requested.

Amendments

Claim 39 is amended to correct a typographical error in dependency. Claims 57-61 recite that both the gestagen and the estrogen are administered orally. See, e.g., page 11, lines 10-13. Claims 62-66 recite that menstrual bleeding occurs at the end of the period. See, e.g., page 8, lines 1-4. Claims 67-69 are dependent upon claim 14 and recite further aspects of applicants' invention. See, e.g., examples 1-8 at pages 9-10.

Rejection under 35 USC § 112, first paragraph

Claim 3-7 and 14-30 are rejected under 35 U.S.C. § 112, first paragraph on grounds of alleged lack of enablement. This rejection is respectfully traversed.

Contrary to the assertion in the rejection, Applicants' disclosure provides more than

sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention. The specification provides examples of gestagens and estrogens for use in the claimed method as well as suitable administration dosages. In addition, in Applicants' examples 1-8 specific method embodiments are described. Thus, the assertion that "no guidance" is provided is clearly wrong. Based on the information in the disclosure and the information available within the art, one of ordinary skill in the art can practice the claimed invention without undue experimentation.

In the rejection, it is argued that the state of the art shows that each combination is critical. It is not clear what is intended by this assertion. However, what is clear is that the prior art of record in their disclosures and claims refer to gestagens and estrogens generally. See, for example, the claims of Gast, Konnincx, Hodgen, and Jager. In each of these references, the claims refer both to estrogens and gestagens in general.

In the rejection, it is alleged that the claims are broad and the specification does not include any *in vivo* or *in vitro* test data. However, it is respectfully submitted that the claims are not broad, especially in light of the state of the art, nor is it required that *in vivo* or *in vitro* test data be presented in the specification.

Furthermore, the field of oral contraceptives is a well developed field. One of ordinary skill in this relevant art is well aware of procedures used for both *in vivo* or *in vitro* testing of oral contraceptive preparations. See, for example, Hodgen (U.S. 5,898,032) regarding *in vivo* studies using monkeys. Moreover, such examples are not needed to objectively enable one of ordinary skill in the art. See, for example, the disclosures of Konnicx, Gast and Jager, all of which disclose oral contraceptives using particular dosage regimens but do not present any *in vivo* or *in vitro* tests. By now it is well settled law that one of ordinary skill in the art need not disclose that which is well known in the art. See, e.g, *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 231 USPQ 81 (Fed. Cir. 1986).

The rejection asserts that without *in vivo* or *in vitro* data, one of ordinary skill in the art "would be at a loss as to where to begin." This argument simply ignores the fact that applicants' disclosure gives examples of gestagens and natural estrogens for use in the claimed method, as well as specific examples of dosage regimes. Here again, see, e.g., applicants' examples in the specification.

Moreover, as discussed above, in vitro and in vivo test models are well known within this

art. Thus, determining the relative efficacy of any particular combination of gestagen and natural estrogen requires no more than routine experimientation.

All that is required under the statue is objective enablement. It is not required that applicants' disclosure presents in vivo or in vitro test results. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112 unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). Furthermore, as stated in *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (CCPA 1971), the PTO must have adequate support for its challenge to the credibility of applicant's statements of utility. See also *In re Bundy*, 209 USPQ 48 (CPA 1981).

Also, it is by now well settled law that the test for enablement is not whether any experimentation is needed but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988)

In view of the above remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with no more than routine experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Rejection(s) Under 35 USC § 103 in view of Weiner et al.

In the Office Action claims 3-7 and 14-30 are rejected as being obvious in view Weiner at al. This rejection is respectfully traversed.

Weiner et al. disclose a treatment for contraception in which three silastic rods impregnated with 40 mg d-norgestrel are implanted in to the forearms of four patients are left in place for 100-458 days. After about 300 days of treatment, the patients were given a daily oral dose of 50 μg of ethynylestradiol, a synthetic steroid (see attached excerpt form The Merck Index, 11th Edition (1989)), for 21 days. Weiner et al. disclose that its synthetic estrogen increases the concentration of sex hormone binding globulin in plasma. Weiner et al. does not disclose that the dosage regime provides cycle control and regular menstrual bleeding.

In the rejection, it is alleged that it would be obvious "to prepare additional compositions" involving administering gestagen in a first phase and gestagen/estrogen in a second phase. The only rationale for this conclusory argument is the allegation that the "prior art teaches similar combination."

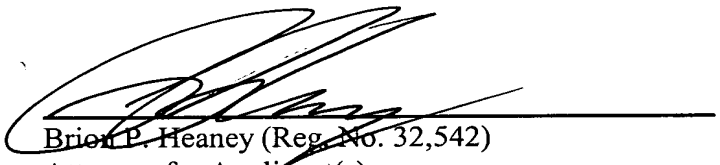
But, Weiner et al. disclose the use of a synthetic estrogen, not a natural estrogen. Further, Weiner et al. provide no suggestion of using other combinations. No other agents other than d-norgestrel and ethynylestradiol are mentioned. The mere ability to modify a disclosure does not by itself establish obviousness. Instead, there most be some motivation established to modify the prior art. See, e.g., *In re Gordon,* 221 USPQ 1125, 1127 (Fed. Cir. 1984) and *In re Laskowski*, 10 USPQ 2d 1397, 1398 (Fed. Cir 1989). In the instant case, no such motivation is presented.

Weiner et al. fails to provide any motivation that lead one of ordinary skill in the art to modify the disclosed method to achieve a method having a dosage regimen (combination and dosage schedule) in accordance with the claimed invention. An assertion of obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. To assess this determination, the hypothetical person has the relevant

prior art in from of him, but has **no knowledge of applicants' invention**. Motivation is not established simply by assuming that the prior art can be modified. It is more than this. Motivation describes the rationale as to why one would be directed toward making particular modifications.

For the reasons discussed above, withdrawal of the prior art rejection and allowance of the application are respectfully requested.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

--39. A method according to claim 38 ~~31~~, wherein the second phase is the last 8 to 10 days of said 28 - 84 day period.--